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CH-A- 485 464  
GB-A- 746 782  
US-A- 1 510 260  
US-A- 2 762 411

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**EP 0 274 345 B1**

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## Description

The present invention is directed to capsules which are divisible by the user into accurate individual dosage units.

5 It is desirable for a patient to be able to administer medicine to him or herself in varying dosages. Thus, a patient may begin medication in larger dosages, and then proceed to smaller dosages, or vice versa, as treatment progresses. Also, different dosages may be desirable for different individuals. Some drugs require monitoring of drug blood level until the patient is stabilized and divisible dosage forms provide a non-complicated procedure for achieving this.

10 In the case of tablets, the need for variable dose administration is easily met, since tablets are breakable into smaller units and sometimes may be scored to facilitate breaking into accurate dosage units.

In the case of a capsule however, breaking or division is not ordinarily possible without destroying the integrity of the capsule and losing some or all of the contents.

15 While providing capsules in varying sizes is possible, it may not be feasible to predict in advance how many capsules in which sizes are necessary for a given patient. In addition, production of capsules in varying sizes complicates the manufacturing process and adds to the patients' cost in the event the dosage must be changed.

Additionally, divisible capsules are desirable since they may be used to separate drugs which are interactive, for example, propoxyphene in its hydrochloride or other suitable salt form and aspirin or sodium 20 meclofenamate and codeine sulphate. Further, they may be arranged so as to formulate a portion of the capsule to be slow releasing while the other portion furnishes drug in a readily available fast-dissolving form, or to include two or three sections all having modified release properties which will afford optimal drug blood levels or by attaching a separate section which has enteric properties.

25 While divisible capsules are known in the prior art, it is believed that the capsules provided by the present invention afford advantages not heretofore realized.

EP-A-0 141 397 discloses a divisible capsule which when undivided is in the shape of a conventional capsule. The capsule is divisible along a plane running along the entire length of the capsule and bisecting it by twisting the two "half capsule" parts away from each other. The result is two capsule units, each of which has a cross-section in the shape of a semi-circle and a flat, planar surface which previously had been 30 connected to the flat, planar surface of the other capsule unit.

The disadvantage of this configuration is that the unfamiliar shape of the "half-capsule", which includes a flat surface, may be unpalatable for the patient to swallow. Additionally, due to the unusual shape of each capsule unit, it is not possible to use conventional capsule filling equipment to fill the capsule units with medicine.

35 US-A-1510260 discloses a package containing a plurality of gelatinuous hollow bodies, each having a rounded, closed end and, an open end, the hollow bodies being nested in series, with the last body of the series being sealed by a closure member.

GB-A-2,148,841 discloses divisible capsules which are formed with integrally molded connection elements. For example, a number of capsule bodies would be manufactured with integrally molded webs 40 between and connecting adjacent capsule bodies, while the capsule caps might also have such integrally molded connection elements.

The disadvantage of this arrangement is that conventional capsule bodies and caps cannot be used, and the need for integrally moulded interconnection elements considerably complicates manufacture.

45 It is thus an object of the present invention to provide a divisible capsule which separates into capsule units which are of familiar and palatable shape.

It is a further object of the present invention to provide a divisible capsule which may utilize conventional capsule bodies or caps.

It is still a further object of the invention to provide a divisible capsule which is relatively easy and straightforward to manufacture and which permits the use of conventional capsule filling equipment.

50 According to the present invention there is provided a capsule which is divisible by the user into accurate individual dosage units, comprising at least two dosage units, each of which is capable of holding a desired medicinal preparation, and is of substantially cylindrical shape, the dosage units being detachably joined to one another in such a manner that their respective longitudinal axes are approximately co-linear in the assembled capsule, wherein each said individual dosage unit is sealed by a closure.

55 If such a divisible capsule has two dosage units, the above objects are accomplished by providing a divisible capsule which is comprised of first and second dosage units, each of which is cylindrical about an axis along the major part of its length, and wherein the capsule units are detachable joined to each other in such manner that the longitudinal axes of the respective capsule units are approximately co-linear.

Preferably at least two of the dosage units of the divisible capsule are terminal dosage units each of which has a first closed, preferably rounded end, and a second open end being sealed by a closure, and wherein each of the closures abuts the neighbouring dosage unit to which it is detachably joined in the assembled capsule. The divisible capsule may further include at least one intermediate dosage units having  
 5 two open ends both of which are sealed by a closure and wherein each of the closures of the intermediate dosage unit abuts the closure of the neighbouring dosage unit, to which the intermediate dosage unit is detachably joined in the assembled capsule.

As used herein, the term "cylindrical" encompasses tubular shapes having circular cross-sections such as elliptical cylinders. While a circular cylindrical shape is preferred, substantially cylindrical capsules of  
 10 other shapes are contemplated. Thus, those having octagonal, hexagonal, square, or other geometrical cross sections are operable. Capsule shapes which resemble tablets (i.e., which are not significantly elongated) could also be used.

The capsule units are detachably joined to each other by various expedients including connection by adhesive, an annular band, and mechanical locking means. Such an annular band may further comprise  
 15 constructive regions and/or perforations.

The invention will be better appreciated by referring to the accompanying drawings in which:

Figures 1-4 are illustrations of a divisible capsule in accordance with several embodiments of the invention.

Figures 5-7 illustrate a method of making the divisible capsules of the invention

20 Figure 8 relates to a method of making the embodiment of Figure 3.

Figure 9 illustrates the assembly of a divisible capsule in accordance with a further embodiment of the invention.

Figure 10 illustrates the divisible capsule shown in Figure 9 as assembled.

Figure 11 shows the assembly of a divisible capsule in accordance with still a further embodiment of the  
 25 invention.

Figure 12 shows the divisible capsule of Figure 11 as assembled.

Figure 13 shows the assembly of a divisible capsule in accordance with still a further embodiment of the invention.

Figure 14 shows the embodiment of Figure 13 as assembled.

30 Figure 15 shows the assembly of a divisible capsule in accordance with still a further embodiment of the invention.

Figure 16 shows the divisible capsule of Figure 15 as assembled.

Figure 17 shows the assembly of a divisible capsule which is comprised of three units.

Figure 18 shows the divisible capsule of Figure 17 as assembled.

35 Figure 19 shows the assembly of a divisible capsule wherein the units are of different diameters.

Figure 20 shows the capsule of Figure 19 as assembled.

Referring to Figure 1, divisible capsule 2 is shown. It is comprised of capsule units 4 and 6, each of which is filled with a desired medicinal preparation 8.

The overall shape of capsule 2 is similar to that of a conventional capsule. That is, each of the capsule  
 40 units 4 and 6 is comprised of a shell which is cylindrical about an axis over the major portion of its length and rounded at one end.

The capsule units are juxtaposed longitudinally so that the cylindrical axes of the respective capsule units are approximately co-linear and are detachably secured to each other in this configuration.

The capsule units are secured by an adhesive and/or an annular band. In the embodiment of Figure 1,  
 45 band 10 is provided which is a thin plastic band of the type sometimes used to secure the bodies and caps of conventional capsules together. The band is perforated at 13 to permit easy separation of the capsule units from each other.

In the embodiment of Figure 2, the band is an annular sleeve 12 having constrictive segments 14 to provide a friction fit. For example, the constrictive segments may be dimples or other raised areas.

50 The capsules depicted in Figures 1 and 2 may be taken as shown to provide a full dose or may be separated from each other by the user to provide a convenient half dose.

It should be noted that while the capsules shown in the illustrative embodiments are bisectable capsules which provide accurate half doses, if desired, the capsules may be dividable in some other proportion, for example, one-third to two-thirds. Conceivably, the capsule could be a series of segments held together as  
 55 shown and used for dose titration purposes.

A method of making the divisible capsules is shown in Figures 5-7. In general a method of making capsules according to the present invention comprises the steps of:

filling at least two substantially cylindrical dosage units with a desired medicinal preparation;

sealing each of the dosage units with a closure; and  
detachably joining the dosage units to each other in such a manner that their respective longitudinal axes are approximately co-linear.

Referring to Figure 5, capsule units 4 and 6 are shown. These may be the caps of conventional capsules, typically comprised of a capsule body and capsule cap, and are frequently made of hard gelatin, but may be made of other suitable material. Instead of the capsule caps, capsule bodies may be used, and as these are longer, it may be desirable to cut them, for example, to two-thirds length.

Referring to Figure 6, the capsule units are filled with a desired medicinal preparation. This, for example, may be in the form of pellets, granules, or viscous or liquid substance. Additionally, the filling step may be performed with the automatic filling machines customarily used to fill conventional capsules.

The capsule units would be filled to within a small distance of the top, for example about one-sixteenth of an inch, and as shown in Figure 7, a thin layer 9 of adhesive paste would be applied to the top to seal in the medicinal preparation.

The capsule units would then be turned inwardly towards each other with the adhesive paste layers abutting each other, and adhesive paste would be applied to the inside and outside of the joint area, after which the joint would be air dried.

After this, a band or sleeve as shown in Figures 1 and 2 would be added.

The adhesive paste used as described above, by way of illustration, could be a polymer solution as follows:

20

<b>HPMC E-15</b>	<b>12% w/w</b>
<b>PEG 3350</b>	<b>2.4% w/w</b>
<b>Alcohol, Denatured</b>	<b>75.4%</b>
<b>Water</b>	<b>10.2% w/w</b>

25

Further embodiments of the divisible capsule of the invention are shown in Figures 3 and 4. In these embodiments, the capsule units are as shown in Figure 8, and each comprises a body portion (22, 24) and a cap (26, 28), wherein the cap (26, 28) has a flat surface and is fitted to snugly fit over the body portion (22, 24).

The caps (26, 28) are bonded to each other with adhesive paste 30 as shown in Figure 3 or by a separately molded section which is sealed to the capsule section by means of solvent welding.

In the embodiment shown in Figure 4, a band 31 having constrictive segments 32 is also added. It is possible that in this embodiment one may dispense with the adhesive paste.

Figures 9-16 illustrate further embodiments of the invention wherein locking mechanical means is used to join the two capsule units.

Referring to Figure 9, capsule units 40 and 44 are shown filled with medicinal preparation 46. Capsule unit 40 is enclosed by cap 42 while capsule unit 44 is closed by adhesive layer 48 or by a friction fit with or without use of a solvent seal.

Intermediate molded locking part 50 is used to secure the two capsule units together. Locking part 50 has open cylindrical recess 53 and annular groove 55. Cap 42 of capsule unit 40 is held snugly in annular groove 55. The molded piece may be made of the same material as the capsule units and the divisible capsule as assembled is shown in Figure 10.

Referring to the embodiment of Figure 11, capsule unit 51 is closed by cap 52 and intermediate molded piece 56 serves both as a closure for capsule unit 54 and as a connecting means to secure the two capsule units together.

Molded piece 56 has open cylindrical recesses 57 and 59, which are separated by flat surface 61. Recess 57 is sized so as to snugly receive cap 52 of capsule unit 51 while recess 59 is sized so as to receive capsule unit 54 in such manner that flat surface 61 acts as a closure for the medicinal preparation in capsule unit 54.

Additionally, the recesses 57 and 59 may have friction fit features such as dimples to enhance the tightness with which the capsule units are held together. The assembled capsule units are shown in Figure 12.

A further embodiment to the invention is shown in Figure 13 wherein cylindrical capsule unit parts 60 and 64 are shown. Each of these capsule unit parts is filled with a desired medicinal preparation, and the capsule unit parts are sealed with rounded or flat caps 62 and 66 respectively. The other end of capsule

unit 60 is provided with a female member 68 which may for example be a cylindrical recess, while capsule unit 64 is provided with a male member 70, which for example may be a cylindrical projection resembling a spike. The male and female members are sized so as to provide a tight friction fit, which may be enhanced by the provision of additional locking means such as one or more dimples on one of the members and a  
 5 corresponding number of detents on the other of the members. Capsule unit parts 60 and 64 may be made of hard gelatin or other known material used for capsule bodies. The assembled divisible capsule is shown at Figure 14.

Figures 15 and 16 illustrate a divisible capsule which is similar to that shown in Figures 13 and 14, except that the locking recess and projection are larger in diameter.

10 Figure 17 illustrates a divisible capsule which is comprised of three units instead of two. The units are body 100/cap 107, body 102/cap 108, and body 101/cap 110. As shown, cap 110 has a cylindrical recess 106 therein, and the units are detachably joined to each other by cylindrical projections 103 and 104, which fit into recesses 105 and 106. Alternatively, centre capsule unit 101/110 could have a recess at each end for receiving projections associated with the end capsule units or could have a projection at each end for  
 15 insertion into recesses which would be associated with the end units. In Figure 18, the capsule shown in Figure 17 is depicted in assembled form.

The embodiment illustrated in Figures 19 and 20 is similar to the embodiment of Figures 15 and 16, except that one of the capsule units is of greater diameter than the other.

The embodiments shown in Figures 13 to 20 may be particularly advantageous in that the divisible  
 20 capsule can be easily separated by a pulling or twisting motion without the necessity of breaking or tearing a part of the capsule.

## Claims

- 25 1. A capsule which is divisible by the user into accurate individual dosage units, comprising at least two dosage units, each of which is capable of holding a desired medicinal preparation, and is of substantially cylindrical shape, the dosage units being detachably joined to one another in such a manner that their respective longitudinal axes are approximately co-linear in the assembled capsule, characterised in that each said individual dosage unit is sealed by a closure.
- 30 2. A divisible capsule according to claim 1, wherein two of the at least two dosage units are terminal dosage units, each of which has a first closed, preferably rounded end, and a second open end which is sealed by a closure, and wherein each of the closures abuts the neighbouring dosage unit to which it is detachably joined in the assembled capsule.
- 35 3. A divisible capsule according to claim 2, further provided with at least one intermediate dosage unit having two open ends, both of which are sealed by a closure, and wherein each of the closures of the intermediate dosage unit abuts the closure of the neighbouring dosage units, to which the intermediate dosage unit is detachably joined in the assembled capsule.
- 40 4. A divisible capsule according to claim 1, 2 or 3, wherein the dosage units are joined together by adhesive.
- 45 5. A divisible capsule according to any preceding claim, wherein the dosage units are joined together by an annular band.
6. A divisible capsule according to claim 5, wherein the annular band has constrictive regions or perforations.
- 50 7. A divisible capsule according to any preceding claim, wherein the dosage units are detachably joined together by mechanical locking means.
8. A divisible capsule according to claim 7, wherein the mechanical locking means includes a hollow cylindrical member open at one end in which it is capable of accommodating a dosage unit.
- 55 9. A divisible capsule according to claim 8, wherein the hollow cylindrical member is further provided with a planar member which acts as a closure for sealing a further dosage unit in the assembled capsule.

10. A divisible capsule according to claim 7, wherein the mechanical locking means comprises interlocking male and female members respectively provided on neighbouring ends of the dosage units as assembled.
- 5 11. A divisible capsule according to claim 10, wherein the male member includes a projection and the female includes a recess.
12. A divisible capsule according to claim 10 or 11, wherein the male and female members have a friction fit when interlocked.
- 10 13. A divisible capsule according to any preceding claim, wherein the closure is in the form of a cap.
14. A method of making a capsule according to any one of claims 1 to 13, which method comprises the steps of:  
15       filling at least two substantially cylindrical dosage units with a desired medicinal preparation;  
          sealing each of the dosage units with a closure; and  
          detachably joining the dosage units to each other in such a manner that their respective longitudinal axes are approximately co-linear.

## 20 Revendications

1. Une capsule, que l'utilisateur peut diviser en doses unitaires individuelles précises, comprenant au moins deux doses unitaires, chacune d'elles étant susceptible de contenir une préparation médicamenteuse souhaitée et étant de forme sensiblement cylindrique, les doses unitaires étant reliées l'une à  
25 l'autre de façon amovible, de manière que leurs axes longitudinaux respectifs soient approximativement colinéaires dans la capsule assemblée, caractérisée en ce que chacune desdites doses unitaires individuelles est scellée par une fermeture.
2. Une capsule sécable selon la revendication 1, dans laquelle deux des doses unitaires, qui sont au  
30 moins au nombre de deux, sont des doses unitaires terminales, chacune d'elles comprenant une première extrémité fermée, de préférence arrondie, et une seconde extrémité ouverte, scellée par une fermeture, et dans laquelle chacune des fermetures vient en butée sur la dose unitaire avoisinante à laquelle elle est reliée de façon amovible dans la capsule assemblée.
- 35 3. Une capsule sécable selon la revendication 2, comprenant au moins une dose unitaire intermédiaire pourvue de deux extrémités ouvertes, toutes deux étant scellées par une fermeture, et dans laquelle chacune des fermetures des doses unitaires intermédiaires vient en butée sur la fermeture des doses unitaires avoisinantes auxquelles la dose unitaire intermédiaire est reliée de façon amovible dans la capsule assemblée.
- 40 4. Une capsule sécable selon la revendication 1, 2 ou 3, dans laquelle les doses unitaires sont reliées par un adhésif.
5. Une capsule sécable selon l'une quelconque des précédentes revendications, dans laquelle les doses  
45 unitaires sont reliées par une bande annulaire.
6. Une capsule sécable selon la revendication 5, dans laquelle la bande annulaire comprend des zones de bridage ou des perforations.
- 50 7. Une capsule sécable selon l'une quelconque des précédentes revendications, dans laquelle les doses unitaires sont reliées entre elles de manière amovible par des moyens de serrage mécaniques.
8. Une capsule sécable selon la revendication 7, dans laquelle les moyens de serrage mécaniques comprennent à une extrémité un élément cylindrique creux susceptible de recevoir une dose unitaire.
- 55 9. Une capsule sécable selon la revendication 8, dans laquelle l'élément cylindrique creux est pourvu en outre d'un élément planaire servant de fermeture pour sceller une autre dose unitaire dans la capsule assemblée.

10. Une capsule sécable selon la revendication 7, dans laquelle les moyens de serrage mécanique comprennent des éléments d'interverrouillage mâle et femelle prévus, respectivement, aux extrémités avoisinantes des doses unitaires après assemblage.
- 5 11. Une capsule sécable selon la revendication 10, dans laquelle l'élément mâle comporte une saillie et l'élément femelle une cavité.
12. Une capsule sécable selon la revendication 10 ou 11, dans laquelle les éléments mâle et femelle sont à ajustage à frottement lorsqu'ils sont verrouillés l'un à l'autre.
- 10 13. Une capsule sécable selon l'une quelconque des précédentes revendications, dans laquelle la fermeture a la forme d'une calotte.
14. Un procédé de fabrication de capsules selon l'une quelconque des revendications 1 à 13, ledit procédé comprenant :  
15 le remplissage d'au moins deux doses unitaires sensiblement cylindriques avec une préparation médicamenteuse souhaitée,  
le scellement de chacune des doses unitaires par fermeture, et  
l'assemblage jointif des doses unitaires entre elles, de façon amovible, de manière que leurs axes  
20 longitudinaux respectifs soient approximativement colinéaires.

#### Patentansprüche

1. Kapsel, welche vom Verwender in genaue Einzeldosiseinheiten geteilt werden kann, welche zumindest  
25 zwei Dosiseinheiten umfaßt, wobei jede derselben eine gewünschte Arzneimittelpräparation enthalten kann und im wesentlichen von zylindrischer Gestalt ist, wobei die Dosiseinheiten so miteinander trennbar verbunden sind, daß ihre jeweiligen Längsachsen in der zusammengefügt Kapsel etwa co-linear sind, dadurch gekennzeichnet, daß jede Einzeldosiseinheit mit einem Verschuß versiegelt ist.
- 30 2. Teilbare Kapsel nach Anspruch 1, worin Zwei der zumindest zwei Dosiseinheiten End-Dosiseinheiten sind, wobei jede derselben ein erstes geschlossenes, vorzugsweise abgerundetes Ende und ein mit einem Verschuß versiegeltes, zweites offenes Ende aufweist, und wobei jeder der Verschlüsse an die benachbarte Dosiseinheit, mit welcher er in der zusammengefügt Kapsel trennbar verbunden ist, stößt.
- 35 3. Teilbare Kapsel nach Anspruch 2, welche weiters mit zumindest einer Zwischendosiseinheit mit zwei offenen Enden versehen ist, welche beiden Enden mit einem Verschuß versiegelt sind, und wobei jeder der Verschlüsse der Zwischendosiseinheit an den Verschuß der benachbarten Dosiseinheiten, mit welchen die Zwischendosiseinheit in der zusammengefügt Kapsel trennbar verbunden ist, stößt.
- 40 4. Teilbare Kapsel nach Anspruch 1, 2 oder 3, worin die Dosiseinheiten mit Klebstoff zusammengefügt sind.
5. Teilbare Kapsel nach irgendeinem vorhergehenden Anspruch, worin die Dosiseinheiten mit einem  
45 ringförmigen Band zusammengefügt sind.
6. Teilbare Kapsel nach Anspruch 5, worin das ringförmige Band sich verengende Bereiche oder Perforationen aufweist.
- 50 7. Teilbare Kapsel nach irgendeinem vorhergehenden Anspruch, worin die Dosiseinheiten mit mechanischen Verschußmitteln miteinander trennbar verbunden sind.
8. Teilbare Kapsel nach Anspruch 7, worin das mechanische Verschußmittel ein an einem Ende offenes, hohles zylindrisches Element, worin eine Dosiseinheit aufgenommen werden kann, umfaßt.
- 55 9. Teilbare Kapsel nach Anspruch 8, worin das hohle zylindrische Element weiters mit einem ebenen Element versehen ist, welches in der zusammengefügt Kapsel als ein Verschuß zur Versiegelung einer weiteren Dosiseinheit wirkt.

10. Teilbare Kapsel nach Anspruch 7, worin das mechanische Verschlußmittel ineinandergreifende männliche bzw. weibliche Elemente, welche an benachbarten Enden der Dosiseinheiten zur Zusammenfügung vorgesehen sind, umfaßt.
- 5 11. Teilbare Kapsel nach Anspruch 10, worin das männliche Element einen Vorsprung und das weibliche eine Aussparung umfaßt.
12. Teilbare Kapsel nach Anspruch 10 oder 11, worin die männlichen und weiblichen Elemente beim Ineinandergreifen eine Reibungspassung aufweisen.
- 10 13. Teilbare Kapsel nach irgendeinem vorhergehenden Anspruch, worin der Verschluß die Form einer Kappe hat.
14. Verfahren zur Herstellung einer Kapsel nach irgendeinem der Ansprüche 1 bis 13, welches Verfahren  
15 die folgenden Schritte umfaßt:  
das Füllen von zumindest zwei, im wesentlichen zylindrischen Dosiseinheiten mit einer gewünschten  
Arzneimittelpräparation;  
das Versiegeln von jeder der Dosiseinheiten mit einem Verschluß;  
und  
20 das trennbare Verbinden der Dosiseinheiten miteinander, sodaß ihre jeweiligen Längsachsen etwa co-  
linear sind.

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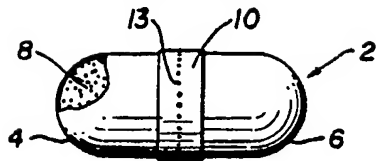
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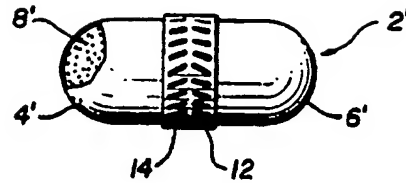
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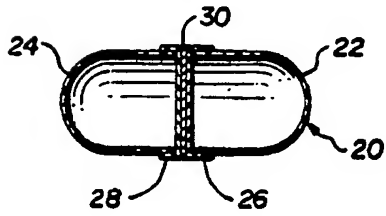
**FIG.1**



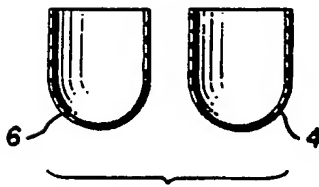
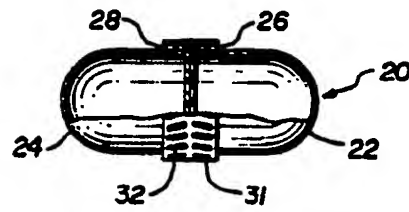
**FIG.2**



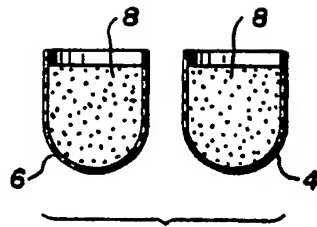
**FIG.3**



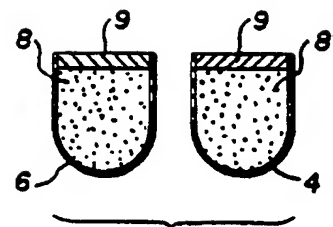
**FIG.4**



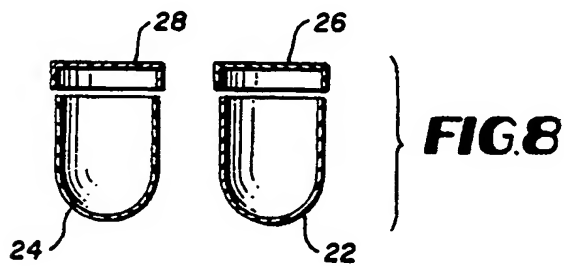
**FIG.5**



**FIG.6**

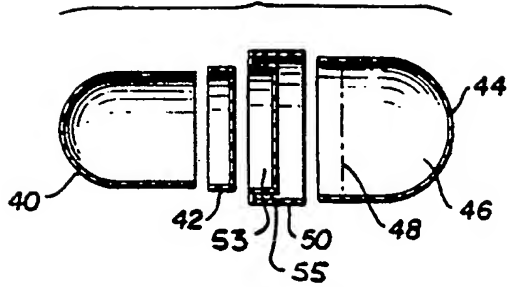


**FIG.7**

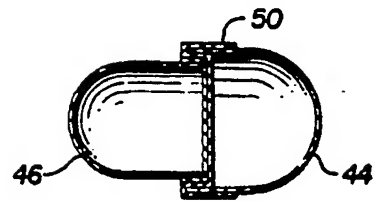


**FIG.8**

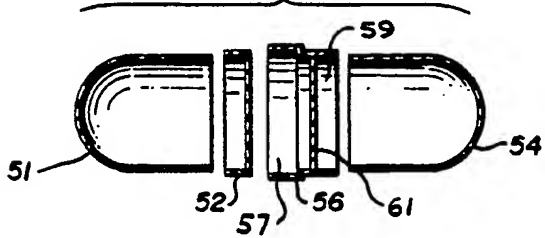
**FIG.9**



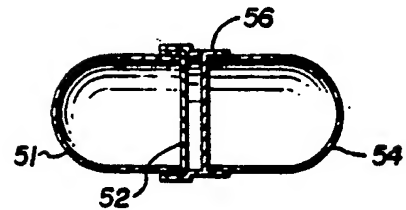
**FIG.10**



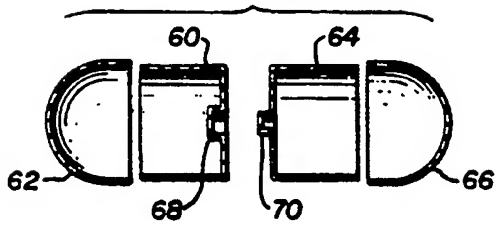
**FIG.11**



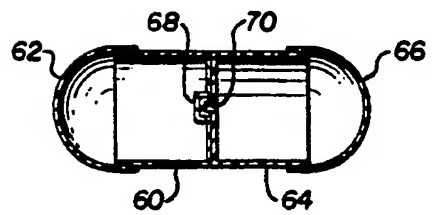
**FIG.12**



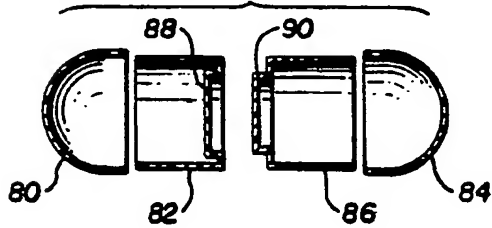
**FIG.13**



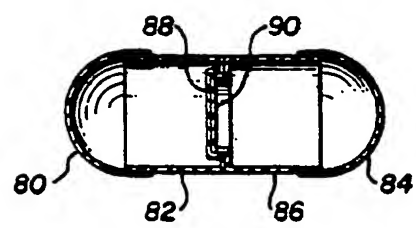
**FIG.14**



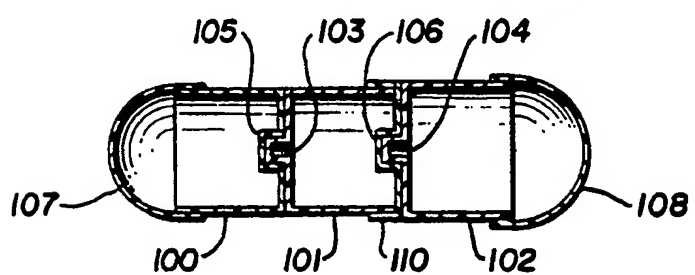
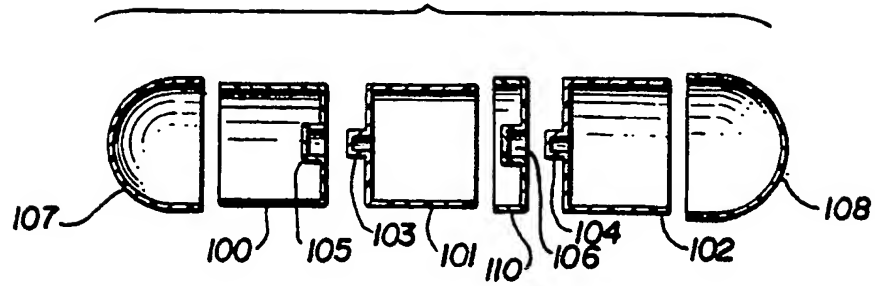
**FIG.15**



**FIG.16**

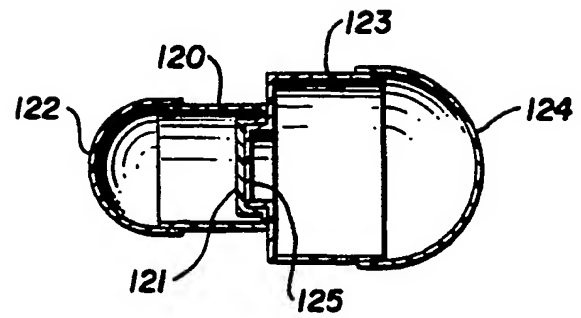
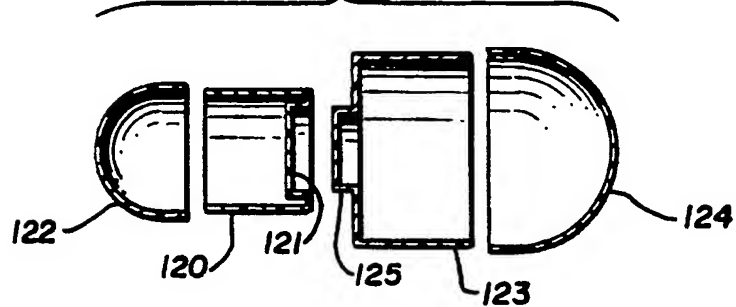


**FIG.17**



**FIG.18**

**FIG.19**



**FIG.20**

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